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10/568,201

09/20/2006

Anthony William Miles

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EXAMINER

VO, HAI

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,201	<b>Applicant(s)</b> MILES ET AL.	
	<b>Examiner</b> Hai Vo	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 20-50 and 52-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-19 and 51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/24/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

***Election/Restrictions***

1. Applicant's election with traverse of Group II, claims 14-19 and 40-51 in the reply filed on 05/11/2009 is acknowledged. Species (i) was further elected by the Attorney or Applicant via a telephone made May 13, 2009. Accordingly, Group II, species (i), claims 14-19 were elected with traverse. The traversal is on the ground that the search of the inventions of Groups I and II has been performed in accordance with the international search report. Applicants then conclude that this indicates that Groups I and II relate to a single general inventive concept and do not lack the same or corresponding special technical feature under PCT Rule 13.2. This is not found persuasive because a single general inventive concept or unity of invention under PCT Rule 13.2 is completely irrelevant to the search of Groups I and II performed together. Instead, the unity of invention is not lacking when none of prior art taken individually or in combination teach or fairly suggest a "special technical feature" of Groups I-II in accordance with PCT Rule 13.2. Since WO 03/026714 reads on the claimed subject matter of both claims 1 and 20, the recited structure in claim 1 does not make a contribution over the prior art, unity of invention is lacking and restriction is appropriate under PCT Rule 13.2. Further, with respect to the species restriction, claim 14 associated with a bone substitute material species (i) is anticipated or obvious over Heide et al (US 2002/0165616) (see rejections below) whereas claim 40 associated with a granular bone substitute material species (ii) is anticipated or obvious over WO 03/30998. As the recited structure of claim 14, species (i) does not make a

contribution over the prior art, unity of the invention is lacking and restriction is appropriate.

The examiner notes that nothing in the restriction requirement made on 04/10/2009 is relied on "a priori" as the evidence of lack of unity of invention. Therefore, Applicants' arguments directed to "the prior" are totally irrelevant to the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicants are reminded of their right to request rejoinder of method claims with the product claims upon indication of the product claims as being allowable. The method claims must be commensurate with the allowed article claims, i.e. have been amended to recite all the features of the allowed article claims. See *In re Ochiai* 37 USPQ2d 1127.

### ***Claim Objections***

3. Claims 17-19 are objected to because of the following informalities: These claims depend from non-elected claim 13. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

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351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 14, 15, 17-19 and 51 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Heide et al. (US 2002/0165616). Since the foam material is completely removed from the final product of the present invention, a porous sintered ceramic does not contain any foam materials. Heide teaches a bone substitute material comprising tubular pores oriented in at least one direction corresponding to a biomechanically or biofunctionally intended direction of growth (paragraphs 45-48). The bone substitute material further includes micropores (paragraph 39). The interconnection of tubular pores and micropores read on the claimed open cells. This at least indicates that the pores have a length in one direction greater than a length in a perpendicular direction. The tubular pores have a diameter ranging from 100 to 2000 microns. There is no teaching or suggestion that the bone substitute material is filled with other material; therefore, the walls defining the tubular pores within the material are hollow. The material has a macroporosity in

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the range of 25 to 50% by volume which is overlapping with the claimed range (paragraph 54). Heide does not specifically disclose the material having a breaking stress of more than 1 MPa. However, it appears that the material meets all the structural limitations and chemistry required by the claim. The bone substitute material comprises tubular pores oriented in at least one direction corresponding to a biomechanically or biofunctionally intended direction of growth. This at least indicates that the pores have a length in one direction greater than a length in a perpendicular direction. The tubular pores have a diameter ranging from 100 to 2000 microns. The walls defining the tubular pores within the material are hollow. The material has a macroporosity in the range of 25 to 50% by volume. Therefore, it is the examiner's position that the breaking stress would be inherently present. This is in line with *In re Spada*, 15 USPQ 2d 1655 (1990) which holds that products of identical chemical composition can not have mutually exclusive properties. It seems from the claim, if one meets the structure recited, the properties must be met or Applicant's claim is incomplete. Accordingly, Heide anticipates or strongly suggests the claimed subject matter.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heide et al. (US 2002/0165616). Heide does not specifically disclose the tubular pores having a length in one direction more than 20% greater than their length in the two other perpendicular directions. Since the diameter/length ratio is recognized as a result-effective variable, differences in the diameter/length ratio will not support the patentability of subject matter encompassed by the prior art unless

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there is evidence indicating such diameter/length ratio is critical or provides unexpected results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the tubular pores with the diameter/length ratio in the range instantly claimed motivated by the desire to facilitate the rapid in-growth of bony tissues without compromising the mechanical strength of the implant.

8. Claims 14-19 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Ito et al. (US 2005/0049715). Since the foam material is completely removed from the final product of the present invention, a porous sintered ceramic does not contain any foam materials. Ito teaches a bone substitute material comprising tubular pores oriented in at least one direction within the material (figures 1-3). The tubular pores have a diameter in x-direction, y-direction and z-direction (table 4). The tubular pores read on the claimed open cells. There is no teaching or suggestion that the bone substitute material is filled with other material; therefore, the walls defining the tubular pores within the material are hollow. The material has a macroporosity in the range of 61% by volume which (table 4). Ito does not specifically disclose the material having a breaking stress of more than 1 MPa. However, it appears that the material meets all the structural limitations and chemistry required by the claim. The bone substitute material comprises tubular pores oriented in at least one direction within the material. The pores have a length in one direction greater than a length in a perpendicular direction (table 4). The tubular pores have a diameter ranging

from 50 to 200 microns. The walls defining the tubular pores within the material are hollow. The material has a macroporosity in the range of 61% by volume. Therefore, it is the examiner's position that the breaking stress would be inherently present. This is in line with *In re Spada*, 15 USPQ 2d 1655 (1990) which holds that products of identical chemical composition can not have mutually exclusive properties. It seems from the claim, if one meets the structure recited, the properties must be met or Applicant's claim is incomplete. Accordingly, Ito anticipates the claimed subject matter.

9. Claim 51 is rejected under 35 U.S.C. 102(b) as being anticipated by Ochi (US 2002/0022885). Ochi teaches a porous sintered ceramic body having a network of open pores that are interconnected to each other (abstract). The network of open pores reads on the claimed positive image of an open celled foam material. The porous body has a macroporosity ranging from 55% to 85% and a mean pore size from 50 to 800 microns (abstract). The porous body has a breaking stress of 280 MPa (example 12). Accordingly, Ochi anticipates the claimed subject matter.
10. Claim 51 is rejected under 35 U.S.C. 102(b) as being anticipated by Imura et al. (US 6,340,648). Imura teaches a porous sintered ceramic body having a network of open pores that are interconnected to each other (abstract). The network of open pores reads on the claimed positive image of an open celled foam material. The porous body has a macroporosity ranging from 55% to 90% and a mean pore size of at least 150 microns (abstract). The porous body has a

breaking strength of 5 MPa (abstract). Accordingly, Imura anticipates the claimed subject matter.

11. It is noted that the examiner disagrees with the citation listed in the International search report filed February 13, 2006 because neither WO 03/026714 nor US 6,136,029 teaches or suggests a bone substitute material having a cellular structure that is oriented such that the cells generally have a length in one direction greater than a length in a perpendicular direction.

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hai Vo/  
Primary Examiner, Art Unit 1794